

Attorney Docket No.: 66530(46590)

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EM006544080US in an envelope addressed to:

MS Sequence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on April 10, 2008
Date

Lyne E. Marks

Signature

Lynn Marcus

Typed or printed name of person signing Certificate

<hr/> Registration Number, if applicable	<hr/> (617) 239-0100 Telephone Number
--	--

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Response to Notice to Comply with Requirements for Nucleotide or Amino Acid Sequence Disclosure (2 pages)
Submission of "Sequence Listing", Computer Readable Copy, And/Or Amendment Pertaining Thereto... (5 pages)
Statement to Support Filing & Submission in Accordance with 37 CFR 1.821-825 (1 page)
Sequence Listing (12 pages)
Disk containing sequence listing
Notice from USPTO (8 pages)
Return postcard



Docket No.: 66530(46590)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Kohji Fukatsu et al.

Application No.: 10/534,081

Confirmation No.: 8962

Filed: May 5, 2005

Art Unit: N/A

For: RECEPTOR FUNCTION REGULATOR

Examiner: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY,
AND/OR AMENDMENT PERTAINING THERETO
FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE
AND/OR AMINO ACID SEQUENCE**

(check and complete this item, if applicable)

1. ☒ This replies to the Office Letter DATED February 14, 2008.

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the serial number from the return post card or the attorney's docket number added.

☒ A copy of the Office Letter is enclosed.

IDENTIFICATION OF PERSON MAKING STATEMENT

2. I, Gregory B. Butler, Ph.D., Esq.

(type or print name of person signing below)

state the following:

ITEMS BEING SUBMITTED

3. Submitted herewith is/are

(check each item as applicable)

- A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. § 1.821(c) and 37 C.F.R. §§ 1.822 and 1.823.
- B. ☐ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. § 1.821(d).
- C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. §§ 1.821(e) and 1.824.
- D. ☐ Please transfer to this application, in accordance with 37 C.F.R. § 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Identifier(s)" of the application as follows:

Computer Readable Form

"Sequence Identifier"

(other application)

(this application)

SEQ ID NO:

SEQ ID NO:

NOTE: "If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference maybe made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified." 37 C.F.R. § 1.821(e).

- E. ☐ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. § 1.821(g).
 - ☐ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. § 1.821(b).
- F. ☐ Because this submission is made in fulfilling the requirement under 37 C.F.R. § 1.821(g), a statement that the submission includes no new matter.
 - ☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. § 1.821(g).

**STATEMENT THAT "SEQUENCE LISTING"
AND COMPUTER READABLE COPY ARE THE SAME
AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER**

4. I hereby state:

(complete applicable item A and/or B)

- A. ☐ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.
- B. ☒ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

STATUS

5. Applicant is

☐ a small entity. A statement:

☐ is attached.

☐ was already filed.

☒ other than a small entity.

6. **EXTENSION OF TERM**

NOTE: *"Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.*

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec. 10, 1985 (1061 O.G. 34-35).

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

(complete (a) or (b) as applicable)

- (a) ☐ Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(1)-(4)) for the total number of months checked below:

	<u>Extension (months)</u>	<u>Fee for other than small entity</u>	<u>Fee for small entity</u>
<input type="checkbox"/>	one month	\$120.00	\$ 60.00
<input type="checkbox"/>	two months	\$450.00	\$ 225.00
<input type="checkbox"/>	three months	\$1,020.00	\$ 510.00
<input type="checkbox"/>	four months	\$1,590.00	\$ 795.00

Fee \$ _____

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured, and the fee paid therefor of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____

OR

- (b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

FEE PAYMENT

8. ☐ Attached is a check in the sum of \$ _____.
- ☐ Charge Account No. _____ the sum of \$ _____.
- A duplicate of this transmittal is attached.

FEE DEFICIENCY

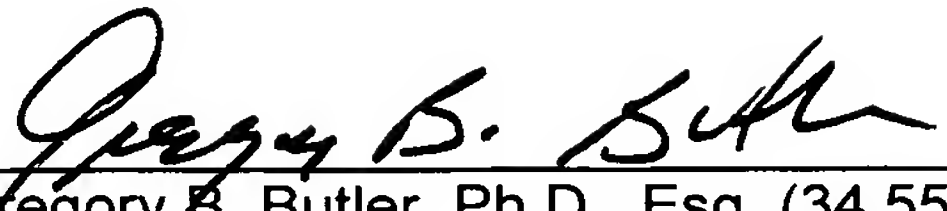
9.

NOTE: *If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.*

10. ☒ If any additional extension and/or fee is required, charge Account No. 04-1105.

SIGNATURE(s)

DATE: 4-10-08


Gregory B. Butler, Ph.D., Esq. (34,558)
Attorney for Applicants
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, MA 02205

Tel. No.: (617) 239-0100
Reg. No. 34,558

- ☐ Inventor
- ☐ Assignee of complete interest
- ☐ Person authorized to sign on behalf of assignee
- ☒ Practitioner of record
- ☐ Filed under Rule 34(a)
- ☐ Registration No.
- ☐ Other



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/534,081	Kohji Fukatsu	3119 USOP

21874
EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

INTERNATIONAL APPLICATION NO.

PCT/JP03/14139

I.A. FILING DATE	PRIORITY DATE
11/06/2003	11/08/2002

CONFIRMATION NO. 8962
371 FORMALITIES LETTER



Date Mailed: 02/14/2008

NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Refer to attachment or PAIR document dated .

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://portal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

FREDERICK SMITH

Telephone: (703) 308-9140 EXT 210



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/534,081		Kohji Fukatsu	3119 USOP

CONFIRMATION NO. 8962

WITHDRAWAL NOTICE

21874
EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205



Date Mailed: 02/14/2008

WITHDRAWAL OF PREVIOUSLY SENT NOTICE

The Notice of Abandonment mailed on 09/25/2006 was sent in error and is hereby withdrawn. A corrected Notice is enclosed. The time period for reply runs from the mail date of the corrected Notice. The Office regrets any inconvenience the error may have caused.

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at
1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/tsirivongxay/

Office of Initial Patent Examination (571) 272-4000 or 1-800-PTO-9199



Docket No.: 66530(46590)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Kohji Fukatsu et al.

Application No.: 10/534,081

Confirmation No.: 8962

Filed: May 5, 2005

Art Unit: N/A

For: RECEPTOR FUNCTION REGULATOR

Examiner: Not Yet Assigned

**RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS
FOR PATENT APPLICATION CONTAINING NUCLEOTIDE
SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

MS Sequence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

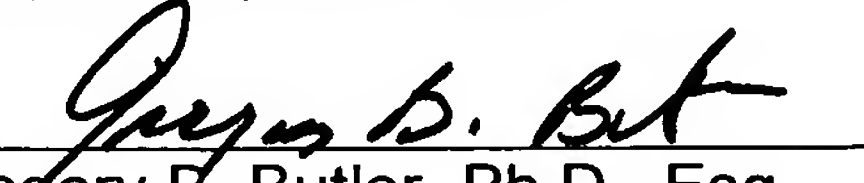
This is in response to the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, dated February 14, 2008. Applicants are submitting their response herewith within the two-month response period set to expire on April 14, 2008.

The U.S. Patent and Trademark Office has taken the position that the previous "Sequence Listing" in computer readable form did not comply with the requirements of Section 1.824 for the stated reason that it contained several raw sequence listing errors. Submitted herewith in connection with the above-referenced patent application is a substitute, computer readable copy of the Sequence Listing that corrects the defects noted in the raw sequence listing. No new matter has been added to the substitute Sequence Listing.

Applicants respectfully request the above-referenced patent application be placed upon the files for examination.

Dated: April 10, 2008

Respectfully submitted,

By 
Gregory B. Butler, Ph.D., Esq.

Registration No.: 34,558

EDWARDS ANGELL PALMER & DODGE
LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 517-5595

Attorneys/Agents For Applicant

STIC Biotechnology Systems Branch

**RAW SEQUENCE LISTING
ERROR REPORT**

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number:

10/534,081

Source:

PGT

Date Processed by STIC:

5-13-05

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/efb/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):
U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05



PCT

RAW SEQUENCE LISTING
PATENT APPLICATION: US/10/534,081

DATE: 05/13/2005
TIME: 14:59:46

Input Set : A:\3119 USOP.seq.txt
Output Set: N:\CRF4\05132005\J534081.raw

3 <110> APPLICANT: FUKATSU, Kohji
4 SASAKI, Shinobu
5 HINUMA, Shuji
6 ITO, Yasuaki
7 SUZUKI, Nobuhiro
8 HARADA, Masataka
9 YASUMA, Tsuneo
11 <120> TITLE OF INVENTION: Modulator of Receptor Function
13 <130> FILE REFERENCE: 3119USOP
C--> 15 <140> CURRENT APPLICATION NUMBER: US/10/534,081
C--> 15 <141> CURRENT FILING DATE: 2005-05-05
15 <150> PRIOR APPLICATION NUMBER: PCT/JP2003/014139
16 <151> PRIOR FILING DATE: 2003-11-06
18 <150> PRIOR APPLICATION NUMBER: JP 2002-324632
19 <151> PRIOR FILING DATE: 2002-11-08
21 <150> PRIOR APPLICATION NUMBER: JP 2003-16889
22 <151> PRIOR FILING DATE: 2003-01-27
24 <150> PRIOR APPLICATION NUMBER: JP 2003-153986
25 <151> PRIOR FILING DATE: 2003-05-30
27 <160> NUMBER OF SEQ ID NOS: 26

Does Not Comply
Corrected Diskette Needed
(PS.1)

ERRORED SEQUENCES

510 <210> SEQ ID NO: 26
511 <211> LENGTH: 21
512 <212> TYPE: RNA
513 <213> ORGANISM: Artificial Sequence
514 <220> FEATURE:
515 <223> OTHER INFORMATION: n stands for deoxy ribothymidine
517 <400> SEQUENCE: 26
E--> 518 nngaacaatc ggtaggctcc g 21

Some of errors shown exist throughout
Sequence Listing. Please check (prior)
sequences for similar errors.

IF it is a DNA
sequence, pls use type
DNA and explain DNA/RNA
in section 2207-
2237.
pls explain source
of genetic
material.
See error explanation
on page 2.

No "Es"
are allowed
in a RNA
sequence.

RAW SEQUENCE LISTING ERROR SUMMARY
PATENT APPLICATION: US/10/534,081

DATE: 05/13/2005
TIME: 14:59:47

Input Set : A:\3119 USOP.seq.txt
Output Set: N:\CRF4\05132005\J534081.raw

Use of <220> Feature(NEW RULES):

Sequence(s) are missing the <220> Feature and associated headings.

Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial Sequence" or "Unknown". Please explain source of genetic material in <220> to <223> section (See "Federal Register," 6/01/98, Vol. 63, No. 104, pp.29631-32)
(Sec.1.823 of new Rules)

Error Explanation:

Seq#:11,12,21,22

VARIABLE LOCATION SUMMARY
PATENT APPLICATION: US/10/534,081

DATE: 05/13/2005
TIME: 14:59:47

Input Set : A:\3119 USOP.seq.txt
Output Set: N:\CRF4\05132005\J534081.raw

Use of n's or Xaa's (NEW RULES):

Use of n's and/or Xaa's have been detected in the Sequence Listing.

Use of <220> to <223> is MANDATORY if n's or Xaa's are present.

in <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

Seq#:23; N Pos. 20,21

Seq#:24; N Pos. 1,2

Seq#:25; N Pos. 20,21

Seq#:26; N Pos. 1,2

VERIFICATION SUMMARY

PATENT APPLICATION: US/10/534,081

DATE: 05/13/2005

TIME: 14:59:47

Input Set : A:\3119 US0P.seq.txt

Output Set: N:\CRF4\05132005\J534081.raw

L:15 M:270 C: Current Application Number differs, Replaced Current Application No
L:15 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:370 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:11, <213>
ORGANISM:Artificial Sequence
L:370 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:11,Line#:370
L:379 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:12, <213>
ORGANISM:Artificial Sequence
L:379 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:12,Line#:379
L:468 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:21, <213>
ORGANISM:Artificial Sequence
L:468 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:21,Line#:468
L:477 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:22, <213>
ORGANISM:Artificial Sequence
L:477 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:22,Line#:477
L:488 M:258 W: Mandatory Feature missing, <221> Tag not found for SEQ ID#:23
L:488 M:258 W: Mandatory Feature missing, <222> Tag not found for SEQ ID#:23
L:488 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:23 after pos.:0
L:498 M:258 W: Mandatory Feature missing, <221> Tag not found for SEQ ID#:24
L:498 M:258 W: Mandatory Feature missing, <222> Tag not found for SEQ ID#:24
L:498 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:24 after pos.:0
L:508 M:258 W: Mandatory Feature missing, <221> Tag not found for SEQ ID#:25
L:508 M:258 W: Mandatory Feature missing, <222> Tag not found for SEQ ID#:25
L:508 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:25 after pos.:0
L:518 M:258 W: Mandatory Feature missing, <221> Tag not found for SEQ ID#:26
L:518 M:258 W: Mandatory Feature missing, <222> Tag not found for SEQ ID#:26
L:518 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:26 after pos.:0
L:518 M:321 E: (1) "t" not allowed in RNA Sequence, NUMBER OF INVALID 't' KEYS:3